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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.												
10/719,916	11/21/2003	Paul Edward Kearney	33766-2037	7002												
33721 TORYS LLP 79 WELLINGTON ST. WEST SUITE 3000 TORONTO, ON M5K 1N2 CANADA	7590 06/27/2007		<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">LIN, JERRY</td></tr></table> <table border="1"><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>1631</td><td></td></tr></table> <table border="1"><tr><td>MAIL DATE</td><td>DELIVERY MODE</td></tr><tr><td>06/27/2007</td><td>PAPER</td></tr></table>		EXAMINER		LIN, JERRY		ART UNIT	PAPER NUMBER	1631		MAIL DATE	DELIVERY MODE	06/27/2007	PAPER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/719,916

Applicant(s)

KEARNEY ET AL.

Examiner

Jerry Lin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 11, 13-20, 23, 25-32, 35, 37-44, 47, 49-56, 59 and 61-110 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 13-20, 25-32, 37-44 and 49-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-8, 11, 13-20, 23, 25-32, 35, 37-44, 47, 49-56, 59 and 61-110 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. In response to the Office Action, mailed October 6, 2006, Applicants have cancelled the elected independent claims and submitted new claims. However, in light of the newly submitted claims, the Examiner has deemed that a species election is required for examination to continue.

#### ***Status of the Claims***

Claims 1-8, 13-20, 25-32, 37-44, and 49-56 are withdrawn as being drawn to a non-elected invention.

Claims 9, 10, 12, 21, 22, 24, 33, 34, 36, 45, 46, 48, 57, 58, 60 are cancelled.

Claims 11, 23, 35, 47, 59, 61-110 are under consideration

#### ***Election/Restrictions***

##### ***Species Election***

2. This application contains claims directed to the following patentably distinct species: (please elect one species)

Species A, 63-66, 68, 73-76, 78, 83-86, 88, 93-96, 98, 103-106, and 108, drawn to obtaining data via liquid chromatography coupled with mass spectrometry (if this species is elected, a subspecies election is also required).

Species B, 67, 69, 77, 79, 87, 89, 97, 98, 107, and 108 drawn to obtaining data from a data file.

3. The species are independent or distinct because:

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Species A and Species B are directed to related processes. The related species are distinct if the (1) the species as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the species do not overlap in scope, i.e., are mutually exclusive; and (3) the species as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the species as claimed are drawn to different design, mode of operation, function and effect. Species A is drawn to wet lab methods of determining a peptide map, whereas Species B is drawn to *in silico* methods of determining peptide maps. These methods require different method steps. In addition, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Furthermore, each of the species would require a separate search for the different method steps. Requiring a separate search would be an undue burden on the Examiner.

4. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 11, 23, 35, 47, 59, 61, 62, 70-72, 80- 82, 90-92, 100-102, and 110 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

### ***Subspecies Election***

5. Species A contains claims directed to the following patentably distinct subspecies: (please elect on subspecies).

Subspecies C, claims 63, 73, 83, 93, and 103, drawn to where one sample is subjected to LC-MS and another sample to LC-MS/MS.

Subspecies D, claims 64, 74, 84, 94, and 104, drawn to all samples are subjected to LC-MS.

Subspecies E, 65, 75, 85, 95, and 105, drawn to where all samples are subjected to LC-MS/MS.

6. The species are independent or distinct because:

Subspecies C, D, and E are directed to related processes. The related subspecies are distinct if the (1) the subspecies as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the subspecies do not overlap in scope, i.e., are mutually exclusive; and (3)

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the subspecies as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the subspecies as claimed are drawn to different methods of detecting and separating a biological sample. Since each subspecies would require a different method steps, the each subspecies has a materially different design and mode of operation. In addition, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Furthermore, each of the subspecies would require a separate search for the different method steps. Requiring a separate search would be an undue burden on the Examiner.

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed subspecies for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 11, 23, 35, 47, 59, 61, 62, 70-72, 80- 82, 90-92, 100-102, and 110 are generic.

Applicant is advised that a reply to this requirement must include an identification of the subspecies that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional subspecies which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are

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added after the election, applicant must indicate which are readable upon the elected subspecies. MPEP § 809.02(a).

***Requirement***

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

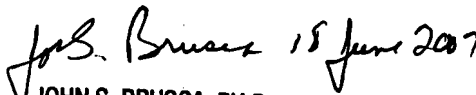
**Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
JL

  
JOHN S. BRUSCA, PH.D  
PRIMARY EXAMINER